UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

JANE DOE 1 and JANE DOE 2, individually and on Behalf of All Others Similarly Situated, Plaintiffs, v. ALLERGAN, INC. f/k/a INAMED CORPORATION, ALLERGAN USA, INC., and ALLERGAN plc, Defendants.	Case No. 19-9151 **CLASS ACTION COMPLAINT** Jury Trial Demanded

Plaintiffs Jane Doe 1 and Jane Doe 2 by their attorneys Wittels Law, P.C. bring this action individually and on behalf of a class of persons defined below, against Defendants Allergan, Inc., Allergan USA, Inc., and Allergan plc (collectively, "Defendants" or "Allergan") and allege the following with knowledge as to their own acts, and upon information and belief as to all other acts:

SUMMARY OF THIS CLASS ACTION TO RECOVER FOR DEFENDANTS' VIOLATIONS

1. Allergan manufactures and sells saline-filled and silicone-filled implants and tissue expanders known as BIOCELL.

2. In response to mounting serious health and safety concerns, Allergan's BIOCELL textured implants were banned completely from the European market in December 2018. Notwithstanding this ban, BIOCELL continued to sell this banned product to women in the United States without any warning or concern to properly advise women of this drastic step taken by regulators in Europe.

3. With no knowledge of the ban or the overwhelming danger posed by having BIOCELL implants inserted in her body, Plaintiff Jane Doe 1 who resides in Westchester County underwent reconstructive breast surgery with BIOCELL textured implants on June 21, 2019. Barely a month later at the end of July 2019, the Allergan Defendants issued a nationwide and worldwide recall of their BIOCELL implants in response to pressure from the United States FDA and regulators in Europe. Plaintiff Jane Doe 1, like Jane Doe 2 and the many thousands of other women who likewise had BIOCELL implants, was utterly shocked at this bombshell news and beside herself with fear.

4. As of July 6, 2019 Medical Device Reports submitted to the U.S. Food and Drug Administration ("FDA") showed that 481 of the 573 unique cases of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) reported worldwide were associated with Allergan's BIOCELL implants.

5. BIA-ALCL is a type of non-Hodgkin's lymphoma – a cancer of the immune system. In most cases, BIA-ALCL is found in the scar tissue and fluid near the implant, but it can also spread through the body. BIA-ALCL can lead to death, especially if not treated promptly. BIA-ALCL can be treated with surgery to remove the implant and surrounding scar tissue and may also require treatment with chemotherapy and radiation treatment. Testing for BIA-ALCL is invasive and symptoms may occur well after the surgical incision has healed, often years after receiving the implant.

6. In a July 24, 2019 announcement, the FDA stated that the risk of developing BIA-ALCL with Allergan BIOCELL textured implants is about six times greater than that of becoming ill with textured implants from other manufacturers available in the U.S. Of the 33 deaths caused by BIA-ALCL, Allergan was the known implant manufacturer for 13 patients. Dr.

Amy Abernethy, principal FDA deputy commissioner stated: "Based on new data, our team concluded that action is necessary at this time to protect the public health." She further stated: "Once the evidence indicated that a specific manufacturer's product appeared to be directly linked to significant patient harm, including death, the FDA took action."

7. In conjunction with its July 24, 2019 announcement, the FDA requested that Allergan voluntarily recall the product in response to this study. In response, Allergan issued a worldwide recall of BIOCELL on July 24, 2019 and announced that BIOCELL would no longer be sold or distributed in any market. To add insult to injury, Allergan announced that it would not reimburse women for any of the costs associated with surgery to remove and replace its defective implants. Instead, in a cynical move, the company offered to provide just the replacement implants at no charge for women who wanted them – but only if women chose an Allergan brand replacement implant.

8. The products subject to Defendants' recall include Allergan Natrelle Saline-Filled Breast Implants (formerly called McGhan RTV Saline-Filled Mammary Implants), Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly called Inamed Silicone-Filled Breast Implants), Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants, and Allergan tissue expanders for the breast implants with BIOCELL texturing.

9. In order to conceal the risks of BIOCELL products from doctors and from the public, Defendants violated the federal law that requires Allergan to report adverse events to the FDA by submitting Allergan's adverse event reports with incorrect manufacturer names, such as "Santa Barbara" and "Costa Rica" rather than "Allergan."

10. While Plaintiffs and the Class remain exposed to the deadly risk of BIA-ALCL associated with Defendants' BIOCELL products, Allergan received a substantial benefit from,

upon information and belief, selling tens of thousands of these products from 2006 through July 24, 2019. Plaintiffs and the Class will be forced to expend substantial sums to remove the recalled implants, for surgical and diagnostic fees, and/or for medical monitoring and invasive diagnostic procedures only necessary because of their exposure to the risk of contracting BIA-ALCL from Defendants' BIOCELL products.

11. Further, as a result of this recall, Plaintiffs and the Class are suffering tremendous emotional pain and suffering and being forced to expend substantial out of pocket resources to replace the defective BIOCELL implants. Moreover, their suffering is compounded by considerations such as whether to live in fear without removing the worrisome implants or take the necessary steps to have them replaced. Thus, Plaintiffs bring this action against the Allergan Defendants for damages and injunctive relief both individually and on behalf of all women in New York, New Jersey, Delaware, and throughout the United States who unfortunately have or had BIOCELL textured breast implants and tissue expanders implanted in their bodies.

PARTIES

12. Plaintiff Jane Doe 1, identified as such to protect her privacy, was a citizen of the County of Westchester, State of New York at all times relevant to this action. On July 6, 2018 Plaintiff was diagnosed with invasive lobular carcinoma, a kind of breast cancer with the potential to spread to lymph nodes and the rest of the body. In September 2018, in consultation with her doctors, Plaintiff underwent a bilateral mastectomy, the surgical removal of both breasts, to treat her breast cancer. At that time, Allergan tissue expanders were implanted to prepare Plaintiff's body for permanent BIOCELL implants.

13. On June 21, 2019 Plaintiff Jane Doe 1 underwent reconstructive surgery in Westchester County, New York. She was implanted with a BIOCELL recalled product, Natrelle

410 Highly Cohesive Anatomically Shape Silicone-Filled breast implant, Reference number MF-410525. Plaintiff Jane Doe 1 would not have had the recalled BIOCELL product implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures to detect BIA-ALCL. Plaintiff Jane Doe 1 wants the recalled BIOCELL product removed from her body at Defendants' full expense according to an explant process which ensures that any scar tissue is removed together with replacing the recalled implants with implants of her choice. Plaintiff Jane Doe 1 also demands that Defendants reimburse her for all lost income and other out of pocket expenses incurred as a result of her anticipated replacement surgery, together with compensation for her intense pain and suffering caused by the defective implants.

14. Plaintiff Jane Doe 2, identified as such to protect her privacy, was at all times relevant to this action a citizen of the States of New Jersey and more recently Delaware. On September 13, 2006 Plaintiff underwent a double mastectomy in New Jersey where she then resided after she learned that she carried a mutated BRCA 2 gene, which put Plaintiff at substantial risk of developing breast cancer. In 2015, in consultation with her doctors Plaintiff had BIOCELL implants from Allergan surgically implanted into her body. Plaintiff Jane Doe 2 would not have had the recalled BIOCELL product implanted had she known prior to the procedure that implantation with BIOCELL would subject her to greater risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical, and diagnostic fees, medical monitoring, and invasive diagnostic procedures to detect BIA-ALCL.

15. Plaintiff Jane Doe 2 who now resides in Delaware also wants the recalled BIOCELL product removed from her body at Defendants' full expense according to an explant

process which ensures that any scar tissue is removed together with replacing the implants with implants of her choice. Plaintiff Jane Doe 2 further demands that Defendants reimburse her for all lost income and other out of pocket expenses incurred as a result of her anticipated replacement surgery, together with compensation for her intense pain and suffering caused by the defective implants.

16. Defendant Allergan plc is a publicly traded corporation headquartered in Dublin, Ireland. Its administrative headquarters for the United States are located in New Jersey. Allergan plc's administrative headquarters in the United States are located in New Jersey as well as California. Allergan plc does business nationwide, including substantial business in the State of New York.

17. Defendant Allergan, Inc. is a wholly-owned subsidiary of Allergan plc and is incorporated under the laws of Delaware, with its principal place of business in New Jersey. Allergan plc's U.S. Medical Aesthetics division responsible for breast implants is based in Irving, California. Allergan, Inc. does business nationwide, including substantial business in the State of New York.

18. Defendant Allergan USA, Inc. is a wholly owned subsidiary of Allergan plc and is incorporated under the laws of Delaware, with its principal place of business in New Jersey. Allergan USA, Inc. does business nationwide, including substantial business in the State of New York.

19. At all relevant times, each Defendant acted in all aspects as the agent and alter ego of each other.

JURISDICTION AND VENUE

20. This Court has subject matter jurisdiction over this class action pursuant to 28

U.S.C. § 1332 (the "Class Action Fairness Act"). This action meets the prerequisites of the Class Action Fairness Act because the aggregate claims of the Class exceed the sum or value of $5,000,000, the Class has more than 100 members, and diversity of citizenship exists between at least one member of the Class and Defendants.

21. This Court has general jurisdiction over Defendants. Defendants do business in New York through continuous, permanent, and substantial activity in New York.

22. This Court has personal jurisdiction over Defendants because Defendants conduct substantial business in New York and within this District. Defendants have sufficient minimum contacts with New York and intentionally avail themselves of the consumers and markets within New York through the promotion and sale of their products, including the now-recalled BIOCELL products.

23. Venue is proper in this district under 28 U.S.C. § 1391 because Plaintiff Jane Doe 1 resides in the District and because a substantial part of the events giving rise to Plaintiff's claims occurred in this District.

FACTUAL ALLEGATIONS

I. Relevant Background

24. Breast implants are medical devices that are implanted under the breast tissue or chest muscle to replace breast tissue that has been removed as a result of cancer or other trauma or to increase breast size.

25. Tissue expanders are normally used in breast reconstruction and are a type of inflatable, temporary breast implant that stretches the skin and muscle by adding increasing amounts of liquid over time to make room for a more permanent implant in the future.

26. There are two primary types of breast implant products: saline-filled (containing

sterile saltwater) and silicone-filled (containing silicone gel). Breast implants come in various sizes and different gel viscosity. They can have either a smooth or textured surface. Approximately 400,000 women in the United States receive breast implants each year, either for breast reconstruction or for cosmetic reasons.

27. Breast implants were first introduced in the 1960s and began gaining acceptance and popularity in the 1970s. In 1976, Congress passed the Medical Device Amendment to the Federal Food, Drug and Cosmetic Act granting the FDA authority to review and approve new medical devices, including breast implants. Breast implants were initially classified as Class II devices, which required manufacturers to provide assurances that their products would not cause harm to the recipients but did not require them to conduct any formal testing.

28. Reports of health complications associated with breast implants grew during the late 1980s and early 1990s. At the same time, studies began to sound the alarm about the dangers of silicone implants and their link to cancer. In response to public concern and growing scientific scrutiny, the FDA re-classified both saline-filled and silicone-filled breast implants as Class III devices, meaning they posed a potential unreasonable risk of illness or injury. In 1991, the FDA began requiring Premarket Approval Applications ("PMAs") for breast implants.

29. Amid growing concern, manufacturers began using surface texturing on breast implants claiming they would reduce the likelihood of common complications. Manufacturers employ different techniques to create their textured implants. These variations result in differences in porosity, complexity, and depth of the texturing on the implant's surface. Allergan's BIOCELL implants use a texturing process called "lost salt" which uses a layer of salt crystals with a thin overcoat of silicone that is then cured in a laminar flow oven. After the surface is cured, the salt on the surface is washed away leaving a pitted surface with random

indentations.

30. In 1992, the FDA issued a moratorium on the sale of silicone-filled breast implants due to increasing concerns about their safety. At the time, McGhan (later Inamed) and Mentor Corporation were the only silicone breast implant manufacturers left in the U.S. market.

31. During the late 1990s and early 2000s, McGhan and Mentor began long-term clinical studies for their silicone implants.

32. Allergan acquired Inamed in 2006. This acquisition was at least partly motivated by the fact that the FDA appeared to be on the verge of lifting the moratorium on silicone implants and Inamed was already selling silicone implants outside of the United States.

33. The FDA lifted the moratorium on silicone implants in 2006. Allergan began selling its Inamed Silicone-Filled Breast Implants in the United States shortly thereafter.

I. Breast Implants and BIA-ALCL

34. A few years after the FDA's moratorium was lifted in 2006, reports and studies linking breast implants to BIA-ALCL began to emerge. Then in January 2011, the FDA released a report informing the public about a possible association between breast implants and BIA-ALCL. The FDA observed that "ALCL has been found more frequently in association with breast implants having a textured outer shell rather than a smooth outer shell."

35. The risk of ALCL is generally estimated to be 1:300,000, but textured breast implants like Allergan's BIOCELL implants greatly increase this risk. Recent FDA studies have shown that the risk of BIA-ALCL in women with textured implants ranges from 1:3,817 and 1:30,000, between 10 and 78 times riskier than for breast implant patients generally. The American Society of Plastic Surgeons estimates the current risk of BIA-ALCL to be between 1:2,207 and 1:86,029 for women with textured implants.

36. Subsequent studies and reports from international governmental agencies validated the FDA's reported potential link between breast implants and BIA-ALCL, further mounting evidence of the deadly risk of BIOCELL even as Allergan continued to sell the implants. For instance, an analysis in March 2015 identified at least 173 cases and the French National Cancer Institute claimed that "[t]here is a clearly established link between the occurrence of this disease and the presence of a breast implant."

37. On May 19, 2016, the World Health Organization ("WHO") designated BIA-ALCL as a form of T-cell lymphoma distinct from other categories of ALCL that can develop following breast implants.

38. On March 21, 2017, the FDA released a safety communication updating the public on the current understanding of BIA-ALCL. In the Updated Safety Alert, the FDA recognized the WHO's designation that BIA-ALCL can occur after a patient receives breast implants, and stated that "[a]t this time, most data suggest that BIA-ALCL occurs more frequently following implantation of breast implants with textured surfaces rather than those with smooth surfaces."

39. In May 2017, a global analysis of forty governmental databases identified 363 cases of BIA-ALCL, 258 of which had been reported to the FDA.

40. A September 2017 update from the FDA reported that the agency had received a total of 414 medical device reports ("MDRs") related to breast implants and BIA-ALCL, including nine deaths.

41. In December 2018, France's national health regulator refused to renew approval for Allergan textured breast implants. Allergan's BIOCELL implants thus lost their European certification and were subsequently banned from being manufactured or sold in the European

market.

II. Allergan's Repeated Attempts to Conceal the Risks of ALCL Associated with Its Breast Implants.

42. In 1976, Congress passed the Medical Device Amendments ("MDA") to the Federal Food, Drug and Cosmetic Act ("FDCA"). The MDA classified saline-filled breast implants as Class II devices, which required them to be reviewed through a premarket notification process. The MDA permitted the devices to be publicly sold so long as manufacturers later provided "reasonable assurance" of the products' safety and effectiveness. 21 U.S.C. § 360e(d)(2).

43. In 1988 the FDA responded to growing safety concerns by re-classifying both saline-filled and silicone gel-filled breast implants as Class III devices requiring premarket approval ("PMA").

44. Upon final publication of new regulations in April 1991 the FDA began requiring breast implant manufacturers to obtain specific premarket approval by the FDA for any silicone gel-filled breast implants. Through its PMA process, the FDA scientifically evaluates the safety and effectiveness of Class III medical devices. Class III devices are those the FDA considers to create the greatest risk to human safety, necessitating the implementation of special controls, including the requirement to obtain PMA under 21 U.S.C. § 360 prior to marketing the product to the public.

45. The FDA requires certain information in a PMA application in order to evaluation of the safety and efficacy of the medical device at issue. A PMA and/or PMA Supplement Application must provide:

a. Proposed indications for use;

b. Device description including the manufacturing process;

c. Any marketing history;

d. Summary of studies (including non-clinical laboratory studies, clinical investigations involving human subjects, and conclusions from the study that address benefit and risk;

e. Each of the functional components or ingredients of the device;

f. Methods used in manufacturing the device, including compliance with current good manufacturing practices; and

g. Any other data or information relevant to an evaluation of the safety and effectiveness of the device known or that should be reasonably known to the manufacturer from any source, including information derived from investigations other than those proposed in the application from commercial marketing experience.

46. Allergan's Natrelle silicone-filled breast implants are Class III medical devices. These implants received pre-market approval by the FDA in November 2006.

47. As conditions of the 2006 approval, the FDA required Allergan to conduct six post-approval studies to characterize the long-term performance and safety of the company's Natrelle silicone-filled breast implants. The post-approval studies for these breast implants included:

a. Core Post-Approval Studies (Core Studies) – To assess long-term clinical performance of breast implants in women that enrolled in studies to support premarket approval applications. These studies were designed to follow women for 10 years after initial implantation.

b. Large Post-Approval Studies (Large Studies) – To assess long-term outcomes and identify rare adverse events by enrolling more than 40,000 silicone gel-filled breast implant patients, following them for 10 years.

c. Device Failure Studies (Failure Studies) – To further characterize the modes and causes of failure of explanted devices over a 10-year period.

d. Focus Group Studies – To improve the format and content of the patient labeling.

e. Annual Physician Informed Decision Survey (Informed Decision Study) – To monitor the process of how patient labeling is distributed to women considering silicone gel-filled breast implants.

f. Adjunct Studies – To provide performance and safety information about silicone gel-filled breast implants for the period when implants could only be used for reconstruction and replacement of existing implants.

48. The PMA provided that "[f]ailure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act."

49. Even after receiving premarket approval for a Class III device such as the Natrelle implants, manufacturers are subject to a continuous obligation to comply with Medical Device Reporting pursuant to 21 U.S.C. § 360i(a)(1) and 21 C.F.R. § 803.50(a). Relevant to this action, manufacturers are required to file adverse event reports with the FDA.

50. The implant's manufacturer has the primary responsibility for timely and accurately communicating complete, accurate, and current safety and efficacy information related to medical devices, such as Allergan's Natrelle Silicone-Filled breast implants.

51. Manufacturers of Class III devices thus have a duty to vigilantly monitor all reasonably available information, to closely track clinical experiences, and to fully and promptly report all relevant information, specifically but not limited to adverse events, to the FDA, to the healthcare community, and to consumers.

52. According to the FDA, the purpose of filing the reports is to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments.

53. These reports can be accessed on the FDA's Manufacturer and User Facility Device Experience ("MAUDE"). Running a search on MAUDE as of the date of this Complaint generates approximately 300 BIA-ALCL cases and approximately 1,400 injury reports.

54. Instead of accurately reporting adverse events individually each time an injury or malfunction occurred, as required by the FDA, Allergan's practice was to bury evidence of

ruptures and other injuries by reporting them as routine events that did not require public disclosure until 2017. This was done through filing "Alternative Summary Reports" ("ASR") for multiple adverse event reports all at one time, instead of filing an adverse event report for each individual adverse event. The ASRs require less detail and are not publicly available through the MAUDE website.

55. In 2017, the FDA no longer permitted the filing of ASRs. Prior to 2017, there were, on average, fewer than 200 breast implant injuries reported each year. In 2017, this number skyrocketed to 4,567 adverse events, and nearly doubled to 8,242 in the first half of 2018.

56. Due to Allergan's unlawful reporting practices, medical professionals and consumers relying on the public reports would be unable to draw an accurate conclusion about the safety of a particular medical device.

57. Delayed reporting prevents the healthcare community and the public from timely learning of risks which inevitably play a part in their decision-making, including by both physicians and consumers, regarding treatments and procedures, and thereby exposes countless additional women to potential harm.

58. Allergan failed to report adverse events from the post-market approval studies commissioned as part of the implant's PMA approval. If Defendants had not unlawfully concealed these untold incidents, reports suggesting the devices' contribution to serious injury could have been made sooner.

59. Indeed, had Defendants not intentionally failed to comply with their clearly-established post-market surveillance obligations, Plaintiffs and the Class would have decided against implantation.

60. Despite having knowledge and possession of evidence showing Allergan's

Natrelle Silicone-Filled breast implants were dangerous and likely to place consumers' health at serious risk, as detailed further below, Allergan ran roughshod over its FDA-mandated obligations by refusing or recklessly failing to identify, disclose, and warn of the health hazards and risks associated with the product, and about all adverse events that were known to Allergan.

61. Pursuant to 21 C.F.R. § 814.39(d)(1)-(2), Allergan was permitted to unilaterally make "[l]abeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association" in order to "reflect newly acquired information."

62. As described above, from 2006 through the date of Plaintiffs' implants, Allergan continually acquired new information regarding the strong association between its BIOCELL implants and the development of BIA-ALCL; an association that was significantly higher than any other textured breast implant.

63. Based on the newly acquired information, Allergan could have made changes to the directions for use ("DFU") for its Natrelle and BIOCELL implants to add or strengthen the warnings about the causal association between the product and the development of BIA-ALCL.

64. Rather than comply with its FDA-mandate and strengthen the information available about the link between its product and BIA-ALCL, Allergan instead chose to actively conceale its acquired knowledge of the causal link through its manipulation of adverse event reports and other public reports, as described above.

65. Allergan's insufficient follow-up rates and active data concealment campaign, as detailed above, establish and confirm Allergan's reckless and intentional disregard for the safety of hundreds of thousands of women in the United States.

66. Each of the above-cited deficiencies in Allergan's post-market compliance, was a

"failure to comply with any post-approval requirement" and each constituted a ground for withdrawal of the PMA. Defendants' conduct violated Defendants' duties under the law.

67. While Allergan failed to comply with post-approval requirements, including the failures described above, the company continued to commercially distribute its Natrelle and BIOCELL breast implants to Plaintiffs and to other women. As expressly provided in the PMA, such distribution was a violation of federal law.

68. Had Allergan substantially complied with the PMA, rather than flagrantly, recklessly, and intentionally underperforming the post-approval requirements as alleged above, Allergan's disclosures would have led to much wider knowledge of the risks associated with Allergan's products. In addition, Allergan's physician and patient labeling would have materially changed over time, and patients including Plaintiffs, and medical providers including Plaintiffs' physicians, would not have purchased or implanted Allergan's products.

CLASS ACTION ALLEGATIONS

69. Plaintiffs bring this action on behalf of themselves and a Class preliminarily defined as two subclasses ("Subclasses") as follows:

a. The Multistate Class, defined as all individuals in the United States who have been implanted with BIOCELL saline-filled or silicone-filled breast implants or tissue expanders that have been recalled by Allergan.

b. The State Classes, defined as all individuals in the States of New York, New Jersey, and Delaware who have been implanted with BIOCELL saline-filled or silicone-filled breast implants or tissue expanders that have been recalled by Allergan, or who were implanted with BIOCELL implants in the States of New York, New Jersey, and Delaware.

70. Excluded from the Class are Defendants, Defendants' legal representatives, officers, directors, assigns, and successors, or any individual who has, or who at any time during the class period has had, a controlling interest in Allergan; and the Judge(s) to whom this case is assigned, their judicial staffs, and any member of the Judges' immediate family.

71. The claims of Plaintiffs and the Class may properly be maintained as a class action against Defendants pursuant to the provisions of Federal Rule of Civil Procedure 23.

72. The size of the Class is more than 100 individuals. The persons in the Class are so numerous that the joinder of all such persons is impracticable.

73. Plaintiffs are members of the Class. Their claims are typical of the claims of the Class and do not conflict with the interests of any other members of the Class. All members of the Class have been subject to and affected by the same or similar conduct.

74. Plaintiffs will fairly and adequately protect the interests of all Class members because it is in their best interest to vigorously prosecute the claims alleged herein and to obtain full compensation for the illegal conduct of which they complain. Plaintiffs have retained competent and experienced class action attorneys to represent their interests and those of the Class.

75. Questions of law and fact are common to the Class and predominate over any questions affecting only individual members, and a class action will generate common answers to the questions below, which are apt to drive the resolution of this action:

a. Whether Defendants were unjustly enriched by the sale of BIOCELL recalled products;

b. Whether Defendants were negligent in selling BIOCELL recalled products;

c. Whether Defendants failed to warn consumers regarding the risks of the BIOCELL recalled products;

d. Whether Defendants violated federal standards and requirements for the marketing, warning, and reporting of the recalled BIOCELL products;

e. Whether Defendants breached implied warranties connected with the recalled BIOCELL products;

f. The appropriate nature of class-wide equitable relief; and

g. The appropriate measurement of restitution and/or measure of damages to Plaintiffs

and members of the Class.

76. A class action is superior to all other available methods for resolving this controversy because (i) the prosecution of separate actions by Class members will create a risk of adjudications with respect to individual Class members that will, as a practical matter, be dispositive of the interests of the other Class members not parties to this action, or substantially impair or impede their ability to protect their interests; (ii) the prosecution of separate actions by Class members will create a risk of inconsistent or varying adjudications with respect to individual Class members, which will establish incompatible standards for Defendants' conduct; (iii) Defendants have acted or refused to act on grounds generally applicable to all Class members; and (iv) questions of law and fact common to the Class predominate over any questions affecting only individual Class members.

77. Accordingly, this action satisfies the requirements set forth under Fed. R. Civ. P. 23(a) and 23(b).

COUNT I

STRICT LIABILITY-FAILURE TO WARN
(ON BEHALF OF A MULTISTATE CLASS UNDER THE LAWS OF EACH STATE WHERE DEFENDANTS DO BUSINESS AGAINST ALL DEFENDANTS)

78. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the preceding paragraphs as if fully set forth herein.

79. Allergan manufactured, distributed, and/or sold the BIOCELL breast implants implanted in Plaintiffs.

80. Defendants had sole access to information regarding the true risks associated with BIOCELL implants and they had a duty to warn Plaintiffs and the Class members of those risks by submitting accurate adverse event reports and amending its warnings contained within the product DFUs.

81. The BIOCELL breast implants had potential risks that were known or knowable in light of the scientific and medical knowledge that was generally accepted in the scientific and medical community at the time of the manufacture, distribution, or sale of the implant and in light of the injury reports suppressed by Defendants.

82. Allergan failed to warn Plaintiffs and their physicians about the serious risk of using its recalled BIOCELL products, including the greatly increased risk of BIA-ALCL. At the time Plaintiffs received their implants, Allergan knew of the clear causal connection between its BIOCELL breast implants and BIA-ALCL but did not disclose this information. Allergan obtained this knowledge from performing extensive decades-long clinical studies, reviewing scientific studies and literature, FDA communications, government reports, and from complaints from consumers, among other sources.

83. Rather than disclose the truth about the dangers of its BIOCELL implants as required by federal law, Allergan attempted to conceal the true facts by not reporting all adverse events to the FDA and by improperly filing ASRs to avoid public reporting on MAUDE.

84. Allergan also failed to warn Plaintiffs, their physicians, and the public by not submitting accurate adverse event reports that patients and physicians rely on to make informed decisions about selecting the type of breast implants.

85. The recalled BIOCELL products were defective and unreasonably dangerous when they left Allergan's possession because they did not contain adequate warnings, including the greatly increased risk of developing BIA-ALCL.

86. The potential risks presented a substantial danger to Plaintiffs and ordinary consumers when used or misused in an intended or reasonably foreseeable way.

87. Plaintiffs and ordinary consumers would have not recognized the potential for

risks.

88. Allergan failed to adequately warn or instruct concerning the potential risks of recalled BIOCELL products.

89. It was foreseeable to Allergan that failure to adequately warn about the risks of its recalled BIOCELL products would cause irreparable harm to the women who had the products implanted in their bodies, including the types of emotional distress suffered by Plaintiffs.

90. As a result of Allergan's failures to adequately warn, Plaintiffs were harmed as described herein including physical pain and emotional distress. The concealment of information known to Allergan and lack of sufficient warnings to consumers were substantial factors in causing Plaintiffs' harm. If Plaintiffs and their physicians had been provided with the appropriate warnings regarding the causal connection between BIOCELL implants and BIA-ALCL, they would never have used a product with such a high risk of BIA-ALCL.

91. Allergan's breach of its duty to warn has caused Plaintiffs damages including surgical costs of removal of the products, ongoing medical monitoring, and other medical expenses.

COUNT II

NEGLIGENCE
(ON BEHALF OF A MULTISTATE CLASS UNDER THE LAWS OF EACH STATE WHERE DEFENDANTS DO BUSINESS AGAINST ALL DEFENDANTS)

92. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the preceding paragraphs as if fully set forth herein.

93. Defendants had a duty to warn Plaintiffs and Class Members of any risks associated with the recalled BIOCELL implants. Defendants knew or should have known of the true risks with BIOCELL implants but failed to warn Plaintiffs, Class members, and their physicians by concealing information and not submitting accurate adverse action reports. By

submitting misleading adverse event reports, and concealing the risks associated with the recalled BIOCELL implants, Defendants negligently violated their duty of care to Plaintiffs and Class Members and their doctors.

94. Defendants' breach of duty caused Plaintiffs and Class members damages, including the surgical costs of removal of the products and/or the surgical and diagnostic fees and medical monitoring and invasive diagnostic procedures associated with retention of the products.

95. Plaintiffs and Class members would not have purchased, chosen, and/or paid for Allergan's BIOCELL implants had they known that they would be exposed to the deadly risk of developing BIA-ALCL.

96. As a direct result of Allergan's breach of duty, Plaintiffs and the Class suffered damages in an amount to be determined at trial.

COUNT III

NEGLIGENT RECALL
(ON BEHALF OF A MULTISTATE CLASS UNDER THE LAWS OF EACH STATE WHERE DEFENDANTS DO BUSINESS AGAINST ALL DEFENDANTS)

97. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the preceding paragraphs as if fully set forth herein.

98. On July 24, 2019, the FDA requested that Allergan recall its BIOCELL products in the United States. That same day, Allergan voluntarily issued a worldwide recall of BIOCELL products.

99. In issuing this voluntary recall, Allergan assumed duties to Plaintiffs to exercise reasonable care in issuing and implementing the recall.

100. Allergan breached these duties by failing to adequately warn Plaintiffs of the dangers associated with the use of the recalled BIOCELL products and by refusing to pay for the

surgical removal of Plaintiffs' implants despite the clear connection between the recalled BIOCELL products and BIA-ALCL and the continuing deadly risk the implants pose to Plaintiffs' health.

101. As a direct result of Allergan's breach of duty, Plaintiffs have suffered harm in an amount to be determined at trial.

COUNT IV

COMMON LAW FRAUD
(ON BEHALF OF A MULTISTATE CLASS UNDER THE LAWS OF EACH STATE WHERE DEFENDANTS DO BUSINESS AGAINST ALL DEFENDANTS)

102. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the preceding paragraphs as if fully set forth herein.

103. Plaintiffs bring this claim on their own behalf and on behalf of each of the state classes under the laws of the states where Defendants sold and distributed its BIOCELL implants, and on behalf of each member of the individual State Classes under the laws of those States.

104. As discussed above, Defendants (i) sold and distributed its BIOCELL implants to Plaintiffs and the Class despite those implants causal link to a deadly risk of developing BIA-ALCL, and (ii) actively suppressed information and misrepresented the health risks associated with the BIOCELL implants.

105. In deciding to have Allergan's BIOCELL implants surgically implanted into their bodies, Plaintiffs and the Class reasonably relied on these misrepresentations to form the mistaken belief that Allergan's BIOCELL implants were reasonably safe for patients.

106. Defendants' fraudulent conduct was knowing and intentional. The misrepresentations and omissions made by Defendants were intended to induce and actually induced Plaintiffs and Class Members to have the company's BIOCELL implants surgically

implanted into their bodies.

107. Defendants' fraud caused damage to Plaintiffs and the Class, who are entitled to damages and other legal and equitable relief as a result.

108. Defendants' acts were done maliciously, oppressively, deliberately, with intent to defraud, and in reckless disregard of Plaintiffs' rights and well-being to enrich Defendants. Defendants' conduct warrants an assessment of punitive damages in an amount sufficient to deter such conduct in the future, which amount is to be determined according to proof.

COUNT V

FRAUD BY CONCEALMENT
(ON BEHALF OF A MULTISTATE CLASS UNDER THE LAWS OF EACH STATE WHERE DEFENDANTS DO BUSINESS AGAINST ALL DEFENDANTS)

109. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the preceding paragraphs as if fully set forth herein.

110. Plaintiffs bring this claim on their own behalf and on behalf of each member of the Multistate Class under the laws of the states where Defendants sold and distributed BIOCELL implants.

111. Defendants concealed material facts concerning the deadly health risks associated with the company's BIOCELL implants by (i) improperly reporting injuries associated with BIOCELL implants in order to conceal the implants' health risks from the FDA, consumers, and physicians, (ii) failing to inform physicians and patients of the true risks of developing BIA-ALCL associated with the BIOCELL implants, and (iii) minimizing the scope of the risks associated with using the recalled BIOCELL products in communications with the public

112. Defendants' material omissions and misrepresentations were intentional and were committed to protect Defendants' profits, avoid damage to Defendants' image, and to save Defendants money, and Defendants did so at Plaintiffs' expense.

113. The information Defendants concealed was material because Plaintiffs and the Class would not have had Allergan's BIOCELL implants surgically implanted into their bodies had they been made aware of the substantial risk of developing BIA-ALCL associated with the implants.

114. Defendants had a duty to disclose the material information they concealed because this information was known and accessible only to Defendants; Defendants had superior knowledge and access to the facts, and Defendants knew the facts were not known to, or reasonably discoverable by Plaintiffs. Defendants also had a duty to disclose because Allergan made affirmative misrepresentations about its BIOCELL implants which were misleading, deceptive, and incomplete without disclosure of the material information.

115. In deciding to have Allergan's BIOCELL implants surgically implanted into their bodies, Plaintiffs and the Class reasonably relied on Allergan's misrepresentations and omissions to form the mistaken belief that Allergan's BIOCELL implants reasonably safe for patients.

116. Defendants' fraud by concealment caused damage to Plaintiffs and the Class, who are entitled to damages and other legal and equitable relief as a result.

117. Defendants' acts were done maliciously, oppressively, deliberately, with intent to defraud, and in reckless disregard of Plaintiffs' rights and well-being to enrich Defendants. Defendants' conduct warrants an assessment of punitive damages in an amount sufficient to deter such conduct in the future, which amount is to be determined according to proof.

COUNT VI

UNJUST ENRICHMENT
(ON BEHALF OF A MULTISTATE CLASS UNDER THE LAWS OF EACH STATE WHERE DEFENDANTS DO BUSINESS AGAINST ALL DEFENDANTS)

118. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the preceding paragraphs as if fully set forth herein.

119. Plaintiffs and the Class members conferred a tangible and material economic benefit upon Defendants by purchasing recalled BIOCELL implants from 2006 through July 24, 2019. Plaintiffs and Class members would not have purchased, chosen and/or paid for BIOCELL implants had they known that they would be exposed to the risk of developing BIA-ALCL. Despite pressure from the FDA to recall its dangerous implants, Defendants refuse to compensate Plaintiffs for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees and medical monitoring and invasive diagnostic procedures associated with retention of the products.

120. Allowing Defendants to retain the economic benefits they received at the expense of Plaintiffs and the Class under these circumstances would result in Defendants being unjustly enriched at the expense of Plaintiffs and the Class, who have been tragically and unnecessarily exposed to the risk of developing a serious and deadly disease.

121. Defendants' retention of the benefit conferred upon them by Plaintiffs and the Class would be unjust and inequitable.

122. Plaintiffs and the Class suffered damages in an amount to be determined at trial.

COUNT VII

BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY (ON BEHALF OF A MULTISTATE CLASS UNDER THE LAWS OF EACH STATE WHERE DEFENDANTS DO BUSINESS AGAINST ALL DEFENDANTS)

123. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the preceding paragraphs as if fully set forth herein.

124. By operations of law, Allergan—as manufacturer of the recalled BIOCELL products and as the provider of the Limited Warranty—impliedly warranted to Plaintiffs that the BIOCELL implants they were purchasing were of merchantable quality and safe for their ordinary and intended use in the human body as an aesthetic breast enhancement.

125. Allergan breached the implied warranty of merchantability in connection with the sale and distribution of the recalled BIOCELL implants. At the point of sale, the recalled BIOCELL implants —while appearing normal—contained latent flaws rendering them unsuitable and unsafe for use in the human body.

126. Had Plaintiffs and their physicians known the recalled BIOCELL products are unsafe for use in the human body, they would not have purchased them and had them surgically implanted in their bodies.

127. Allergan has refused to provide appropriate warranty relief, as it will not provide surgical fee assistance to patients despite the substantially increased risk of developing BIA-ALCL. Plaintiffs reasonably expected that their implants would not present a substantial risk of bodily harm at the time of their purchases.

128. As a direct and proximate result of Allergan's' breach of the implied warranty of merchantability, Plaintiffs have sustained damages in an amount to be determined at trial.

COUNT VIII

NEW YORK GENERAL BUSINESS LAW § 349
(ON BEHALF OF THE NEW YORK CLASS AGAINST ALL DEFENDANTS)

129. Plaintiff Jane Doe 1 re-alleges and incorporates by reference each and every allegation contained in the preceding paragraphs as if fully set forth herein.

130. Plaintiff Jane Doe 1 brings this claim on her own behalf and on behalf of each Class member who is a New York resident or who was implanted with BIOCELL implants in New York (the "New York Class").

131. New York's consumer fraud statute prohibits "[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state." N.Y. GEN. BUS. LAW §349.

132. Defendants' deceptive sale and distribution of its dangerous BIOCELL implants and its campaign to suppress knowledge of the serious health risks associated with those implants are consumer-oriented in that they are directed at members of the consuming public looking to purchase breast implants. These deceptive acts and practices violate N.Y. GEN. BUS. LAW §349 by, *inter alia*:

i) Engaging in a campaign of suppression that is likely to mislead a reasonable consumer acting reasonably under the circumstances by improperly labelling and reporting consumer health issues associated with Allergan's BIOCELL implants;

ii) Selling and distributing breast implants that significantly increase patients' risk of developing BIA-ALCL; and

iii) Omitting material information by failing to inform consumers of the serious health risks associated with Allergan's BIOCELL implants.

133. The aforementioned acts are unfair, unconscionable and deceptive and are contrary to the public policy of New York which aims to protect consumers.

134. As a direct and proximate result of Defendants' unlawful and deceptive acts and practices, the Plaintiff Jane Doe 1 and the New York Class have suffered injury and monetary damages in an amount to be determined at the trial of this action.

COUNT IX

NEW JERSEY CONSUMER FRAUD ACT
(ON BEHALF OF THE NEW JERSEY CLASS AGAINST ALL DEFENDANTS)

135. Plaintiff Jane Doe 2 re-alleges and incorporates by reference each and every allegation contained in the preceding paragraphs as if fully set forth herein.

136. Plaintiff Jane Doe 2 brings this claim on her own behalf and on behalf of each Class member who is a New Jersey resident or who was implanted with BIOCELL implants in New Jersey (the "New Jersey Class").

137. Defendants are "persons" within the meaning of N.J. STAT. ANN. § 56:8-1(d).

138. Defendants engaged in the "sale" of "merchandise" within the meaning of N.J. STAT. ANN. § 56:8-1(c), (d).

139. The New Jersey Consumer Fraud Act (the "New Jersey CFA") makes unlawful "[t]he act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing concealment, suppression or omission of any material fact with the intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby . . . ." N.J. STAT. ANN. § 56:8-2.

140. Defendants violated the New Jersey CFA by, *inter alia*:

i) Engaging in a campaign of suppression that is likely to mislead a reasonable consumer acting reasonably under the circumstances by improperly labelling and reporting consumer health issues associated with Allergan's BIOCELL implants;

ii) Selling and distributing breast implants that significantly increase patients' risk of developing BIA-ALCL; and

iii) Omitting material information by failing to inform consumers of the serious health risks associated with Allergan's BIOCELL implants.

141. Defendants knew or should have known that their conduct violated the New Jersey CFA.

142. As a direct and proximate result of Defendants' unlawful and deceptive acts and practices, Plaintiff Jane Doe 2 and the New Jersey Class have suffered injury and monetary damages.

143. The New Jersey Class is entitled to recover legal and/or equitable relief including an order enjoining Defendants' unlawful conduct, treble damages, costs and reasonable attorneys' fees pursuant to N.J. Stat. Ann. § 56:8-19, and any other just and appropriate relief.

144. Plaintiffs have complied with N.J. Stat. Ann. § 56:8-20. Within ten (10) days of its filing, Plaintiffs mailed a copy of the initial complaint setting forth claims under the New Jersey CFA to New Jersey's Attorney General.

COUNT X

DELAWARE UNIFORM DECEPTIVE TRADE PRACTICES ACT
(ON BEHALF OF THE DELAWARE CLASS AGAINST ALL DEFENDANTS)

145. Plaintiff Jane Doe 2 re-alleges and incorporates by reference each and every allegation contained in the preceding paragraphs as if fully set forth herein.

146. Plaintiff Jane Doe 2 brings this claim on her own behalf and on behalf of each Class member who is a Delaware resident or who was implanted with BIOCELL implants in Delaware (the "Delaware Class").

147. Defendants are "persons" within the meaning of 6 Del.C § 2531(5).

148. A person or persons violates the Delaware Uniform Deceptive Trade Practices Act (the "Delaware Act") when that person or persons engages in deceptive trade practices which include, *inter alia*, "[r]epresent[ing] that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another" or "[e]ngag[ing] in any other conduct which similarly creates a likelihood of confusion or of misunderstanding." 6 Del.C § 2532.

149. Defendants violated the Delaware Act by, *inter alia*:

iv) Engaging in a campaign of suppression that is likely to mislead a reasonable consumer acting reasonably under the circumstances by improperly labelling and reporting consumer health issues associated with Allergan's BIOCELL implants;

v) Selling and distributing breast implants that significantly increase patients' risk of developing BIA-ALCL; and

vi) Omitting material information by failing to inform consumers of the serious health risks associated with Allergan's BIOCELL implants.

150. Defendants knew or should have known that their conduct violated the Delaware Act.

151. As a direct and proximate result of Defendants' unlawful and deceptive acts and practices, Plaintiff Jane Doe 2 and the Delaware Class have suffered injury and monetary damages.

152. The Delaware Class is entitled to recover legal and/or equitable relief including an order enjoining Defendants' unlawful conduct, treble damages, costs and reasonable attorneys' fees pursuant to Del.C § 2533, and any other just and appropriate relief.

COUNT XI

MEDICAL MONITORING
(ON BEHALF OF A MULTISTATE CLASS UNDER THE LAWS OF EACH STATE WHERE DEFENDANTS DO BUSINESS AGAINST ALL DEFENDANTS)

153. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the preceding paragraphs as if fully set forth herein.

154. As a result of exposure to the recalled BIOCELL implants, the need for future monitoring is reasonably certain. Allergan's textured implants significantly increase the risk of BIA-ALCL and symptoms of BIA-ALCL routinely present years after the BIOCELL product is surgically implanted.

155. Medical monitoring is therefore reasonable in order to properly diagnose the symptoms of BIA-ALCL. This is particularly crucial, as BIA-ALCL is more fatal when not treated in a timely manner.

156. Plaintiffs are therefore entitled to have Allergan pay for the costs of ongoing medical monitoring.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs on their own behalf and on behalf of all other similarly situated

persons, seek the following relief:

A. Certification of this case as a class action pursuant to Rule 23;

B. Designation of Plaintiffs as Representative of the Class and counsel of record as Class Counsel;

C. An award of equitable and injunctive relief, including but not limited to, requiring Defendants to institute a medical monitoring program for Class Members, restitution, and disgorgement of profits;

D. An award of damages of at least $100,000,000, according to proof, to be paid by Defendants, to which Plaintiffs and Class members are entitled;

E. Punitive damages;

F. Pre-judgment interest and post-judgment interest;

G. Reasonable attorneys' fees and costs of the action; and

H. Such other relief as this Court shall deem just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiffs request trial by jury in this action of all issues so triable.

Dated: Armonk, New York
October 2, 2019

By: s/ Steven L. Wittels____

Steven L. Wittels (SW-8110)
J. Burkett McInturff (JM-4564)
Tiasha Palikovic (TP-5697)
WITTELS LAW, P.C.
18 HALF MILE ROAD
ARMONK, NEW YORK 10504
Telephone: (914) 319-9945
Facsimile: (914) 273-2563
slw@wittelslaw.com
jbm@wittelslaw.com
tpalikovic@wittelslaw.com

Counsel for Plaintiff and the Class